

REMARKS

Interview

On December 1, 2008 Applicants' representative requested a telephonic interview as a bona fide attempt to advance prosecution of the present application. However, it was not possible to schedule an interview on time. As such, Applicants cordially request the Examiner for the scheduling of a telephonic interview prior to examination of the claims on the merits.

Claims

Claims 1–5, 9–10 and 19–20 are under examination with claims 6–8 and 11–17 previously withdrawn from consideration due to restriction/election.

Claim amendments

Claim 1 has been amended to delete the functional aspect(s) of the polypeptides of the present invention and complies with the PTO's new written description guidelines, as published in the *Training Materials* (Rev. 1, March 25, 2008).

Claim 19 has been amended as per the Examiner's suggestion.

Amended claim 20 is supported by the disclosure contained in, for example, page 19, 1st complete paragraph of the originally-filed specification.

It is submitted that the claim amendments do not add new matter. Entry thereof is earnestly solicited.

Restriction/election

The restriction of claim 16, which is directed to polynucleotide molecules of the present invention, is inappropriate. A modification of the restricted claims to include claim 16 into the examined claim-set is respectfully requested.

Upon allowance of the generic product claims, Applicants reserve the right to request rejoinder of claims 11–15, which are drawn to a method of using the elected molecule(s) and/or composition(s). "If a product claim is found allowable, process claims that depend from or otherwise require all the limitations of the patentable product may be rejoined." See M.P.E.P. § 806.05. See also, M.P.E.P. §821.04, "Rejoinder."

Formal objections

Applicants are in the process of obtaining a revised sequence disclosure stating the origin of SEQ ID NO: 1 from a vendor specializing in such services. Applicants will file a supplemental

amendment to afford the PTO with these revisions. The Examiner is respectfully requested to hold the objection of the sequence disclosure in abeyance until such can be obtained. See, MPEP 714.02 (b).

The objection of the specification for allegedly failing to provide a BRIEF DESCRIPTION OF THE DRAWINGS is traversed. Applicants submit that the present specification provides a detailed description of each of all the drawings, and as explicitly stated under §608.01(a), the outlining and/or arrangement of the specification into discrete sections is merely “preferred” and not mandatory as alleged in the Office Action. However, in order to facilitate prosecution, the specification has been amended to include this section. No new matter is added. Withdrawal of the objection is respectfully requested.

The objection of the drawings for allegedly failing to recite the sequence identifier number of the polypeptide sequence is moot in view of the amendments to the specification. More specifically, as explicitly stated under MPEP §2429, “the sequence information so conveyed [in the Figures] must still be included in a “Sequence Listing” and the sequence identifier (“SEQ ID NO: X”) must be used, either in the drawing or in the “Brief Description of the Drawings.” (Emphasis added).” The present specification, in view of the amendments presented herein, satisfies this requirement.

The abstract has been amended, rendering the objection thereof moot.

IDS

A new IDS along with a PTO-1449 form containing reference to the Klussman abstract is submitted herewith. Consideration thereof is earnestly solicited.

Rejections under §112, ¶2

Applicants disagree with the PTO’s contention that recitation of “a behavior which is analogous to the AKAP188 polypeptide of SEQ ID NO: 2” renders the claims indefinite. The specification provides a detailed disclosure of AKAP188 activity, including analogous activity. However, in order to facilitate prosecution, the claims have been amended. Support for the amendment of claim 20 can be found in, for example, page 19, lines 10–12 of the originally-filed specification and the disclosure contained in the Examples. Withdrawal of the rejection is respectfully requested.

Claims 2 and 19 have been amended as per the Examiner’s suggestion, thus rendering the rejection thereof under this section moot. Withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. §112, ¶1 (written description)

While applicants may not agree with the agency's interpretation of the elements necessary to meet the statutory requirements of 35 U.S.C. § 112, ¶1, nonetheless, the pending claims have been amended to substantially conform to these.

Present claims 1 and 20 conform to exemplary claims 1 and 2 of Example 11B beginning on Page 39 of the *Training Materials* (Rev. 1, March 25, 2008) of the PTO's new *Written Description Guidelines*. The representative claims are as follows:

Claim 1. (Analogous to present claim 1) An isolated nucleic acid that encodes a polypeptide with at least 85% amino acid sequence identity to SEQ ID NO: 2.

Claim 2. (Analogous to present claim 20) An isolated nucleic acid that encodes a polypeptide with at least 85% amino acid sequence identity to SEQ ID NO: 2; wherein the polypeptide has activity Y.

The guidelines state that both claims 1 and 2 satisfy the requirements set forth under §112, ¶1. For a detailed discussion thereof, Applicants cordially request the Examiner to review the remarks section of the Reply filed June 6, 2008. Withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. §112, ¶1 (enablement)

Reconsideration of this rejection, in view of Applicants' remarks/arguments submitted with the Reply filed June 6, 2008, further in view of the precedential opinion issued by the United States Board of Patent Appeals and Interferences (*Ex parte* Kubin, B.A.P.I. 2007) is earnestly solicited.

Moreover, Applicants cordially traverse the PTO's contention that the specification must provide explicit guidance as to which domains, motifs, or amino acid residues that may be altered in the claimed variant polynucleotide. The art is replete with information on degeneracy of the genetic code, conserved amino acid substitutions, replacement of analogous amino acid residues with structurally similar amino acids, and the like. Examples of such conserved substitutions include, but are not limited to:

- (a) non-polar hydrophobic amino acids: Gly, Ala, Val, Leu, and/or Iso;
- (b) hydroxyl amino acids: Ser, Thr, and/or Tyr;
- (c) amides of dicarboxylic amino acids: Asn and/or Gln;
- (d) amino of dicarboxylic amino acids: Asp and/or Glu;
- (e) basic amino acids: Lys, Arg and/or Orn;
- (f) aromatic amino acids: Phe, Tyr and/or Trp;
- (g) β -functional groups: Cys, Met, Ser, α -aminobutyric acid and/or selenocysteine;
- (h) turn-inducing groups: Pro, 1-amino-2-carboxy cyclohexane, pipecolic acid and ortho-

amino benzoic acid. One skilled in biochemistry also knows that such variant polynucleotide sequences are not limited to degenerate codes or conserved amino acid substitutions, as enantiomeric substitutions and amino acid modifications in accordance with WO 99/62933 or WO 02/38592 are also possible.

To this end, the reference publications enclosed herewith explicitly teach that it is possible to replace single amino acids or groups of amino acids in a polypeptide chain without adversely affecting the activity of the resulting peptides. Methods for carrying out such substitutions, deletions, variations, etc. are known in the art. For example, a skilled artisan may start with a polynucleotide sequence of SEQ ID NO: 1 and conduct site-directed mutagenesis to mutate specific residues in the polynucleotide sequence. The polypeptides that are encoded by such variant polynucleotide sequences can be analyzed, for example, with respect to its primary and secondary structure(s) *a priori*. Other *in vitro* assay techniques comprising the use of recombinant proteins, for example, binding assays, enzymatic assays, activity assays and the like, may similarly be employed. The whole process constitutes nothing more than what is routine in the art. For example, methods for generating functionally analogous polypeptides are described in *Schneider et al* (PNAS, 1998), a copy of which is enclosed herewith for the Examiner's review. See also the enclosed article by Hundrucker (*Biochem J.*, 2006), wherein in Table 2, the results of a binding assay for the determination of the interaction between AKAP78 polypeptide variants and RII α is disclosed.

In view of the above remarks, it is respectfully submitted that Applicants' disclosure provides more than sufficient guidance to objectively enable one of ordinary skill in the art to make and use the claimed invention with an effort that is routine with in the art. Withdrawal of the rejection under 35 U.S.C. §112, ¶1, is respectfully requested.

If there are any remaining issues which can be expedited by a telephone conference, the Examiner is courteously invited to telephone counsel at the number indicated below.

No fees are believed to be due with this response; however, the Commissioner is hereby authorized to charge any fees associated with this response to Deposit Account No. 13-3402.

Respectfully submitted,

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